

**REMARKS**

**I. Status of the Claims**

As proposed herein, claim 1 has been further amended to recite:

A method of decreasing a risk of mortality caused by congestive heart failure in a patient in need of such decrease . . .

Support can be found throughout the specification and claims as originally filed, including, e.g., col. 1, ln. 9-14 ("The present invention relates to a new method of treatment ... for decreasing the mortality of patients suffering from congestive heart failure ...."); col. 3, ln. 59-63 ("carvedilol [is] able to decrease the mortality resulting from CHF in humans by about 67 percent."); col. 6, ln. 61-62 ("This represented a reduction in risk of death by [carvedilol] of 67% ... "). The scope of the claims has not been broadened, and no new matter has been added.

**II. Interview Summary**

Applicants thank Examiner Spivack for her time on September 8, 2005, conducting a telephonic interview with their undersigned representative. Two issues were discussed: (1) the reissue application and (2) consideration of the materials provided with Applicants' Information Disclosure Statement of December 28, 2004.

(1) Concerning the reissue application, the Examiner indicated that the Office's rejection of the reissue application for want of a suitable error for reissue could be overcome by amending claim 1 to recite:

A method of decreasing a risk of mortality caused by congestive heart failure in a patient in need of such decrease . . .

as indicated previously in the first Office Action (January 11, 2005, Office Action, pg. 3) and in the Final Office Action (July 14, 2005, Office Action, pg. 2). Without conceding the propriety of the rejection, claim 1 has now been so amended.

(2) The Examiner confirmed that, as stated in the Final Office Action with respect to the information provided with Applicants' Information Disclosure Statement filed December 28, 2004, "All references have been considered." (July 14, 2005, Office Action, pg. 2.) The Examiner further confirmed that the references crossed out and not initialed on the returned copy of Applicants' IDS Form PTO/SB/08 were considered, and that cross outs and absence of initials merely indicate the Examiner's intent that those materials should not be printed on the face of the reissue patent. The Examiner agreed to confirm in the next action that all references, including those crossed out and not initialed, were considered.

### **III. Supplemental Reissue Declaration**

A Supplemental Reissue Declaration is being filed herewith, to reference the present After Final Amendment and state that "[t]he error upon which reissue is based is the failure of U.S. Patent No. 5,902,821 to recite in the preamble of claim 1 that the method is 'A method of decreasing a risk of mortality caused by congestive heart failure in a patient in need of such decrease . . . .'" As discussed in section II above, Applicants understand that Office's prior rejection of the Reissue Declaration will now be moot.

### **IV. Application Data Sheet**

The Application Data Sheet referenced in Applicants' Response of April 11, 2005, is being filed herewith.

**CONCLUSION**

Applicants respectfully request that this Amendment under 37 C.F.R. § 1.116 be entered by the Examiner, placing the present reissue application with claims 1-30 in condition for allowance. Applicants submit that the proposed amendment of claim 1 does not raise new issues or necessitate the undertaking of any additional search of the art by the Examiner. Therefore, this Amendment should allow for immediate action by the Examiner.

Applicants therefore request the entry of this Amendment, the Examiner's reconsideration and reexamination of the application, and the timely allowance of the present reissue application with claims 1-30.


Please grant any extensions of time required to enter this response and charge any additional required fees to Deposit Account No. 06-0916.

The Examiner is respectfully invited to contact Applicants' undersigned representative by telephone at (202) 408-4092 to address any additional matters pertaining to this application.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,  
GARRETT & DUNNER, L.L.P.

Dated: September 14, 2005

By:   
Mark J. Feldstein  
Reg. No. 46,693